



STATE OF MARYLAND

**DHMH**

Department of Health and Mental Hygiene

*Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary*

**MARYLAND BOARD OF PHARMACY**

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

*Donald Taylor, Board President - LaVerne G. Naesea, Executive Director*

## LONG TERM CARE PHARMACY INSPECTION FORM

### 1. PERMITS AND LICENSES

Corporate Pharmacy Name \_\_\_\_\_

Pharmacy Name-Doing Business as (d/b/a) or Trade Name \_\_\_\_\_

Street Address \_\_\_\_\_

Business Telephone Number \_\_\_\_\_ Business Fax Number \_\_\_\_\_

Inspection Date: \_\_\_\_\_ Arrival Time: \_\_\_\_\_ Departure Time: \_\_\_\_\_

Type of Inspection: Annual Follow-up Previous Date: \_\_\_\_\_

Name of Inspector: \_\_\_\_\_

Yes No

☐ The pharmacy department provides service 24 hours. COMAR 10.34.05.

☐ The pharmacy hours of operation and after hour procedures are provided to the Long Term Care Establishments. COMAR 10.34.05.03B

Pharmacy Hours: \_\_\_\_\_

☐ All permits, licenses, and registrations are posted conspicuously.  
HO §12-311, HO §12-408(b) and HO §12-6B-08

Maryland Pharmacy Permit Number \_\_\_\_\_ Expiration \_\_\_\_\_

CDS Registration Number \_\_\_\_\_ Expiration \_\_\_\_\_

DEA Registration Number \_\_\_\_\_ Expiration \_\_\_\_\_

☐ The pharmacy performs sterile compounding. (If yes, complete Sterile Compounding Inspection Form) COMAR 10.34.19

Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

## 2. PERSONNEL (COMAR 10.34.03.05)

Name of Director of Pharmacy who is charged with compliance with all applicable laws

Maryland License # \_\_\_\_\_ Expiration Date \_\_\_\_\_

Pharmacist Employees	License #	Expiration Date

(Attach list if necessary)

Registered Technicians	Registration #	Expiration Date

(Attach list if necessary)

Ancillary Personnel (non-registered)	Title	Duties

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## 3. PERSONNEL TRAINING

Yes No

- ☐ ☐ There are written policies and procedures to specify duties that may be performed by ancillary personnel under the supervision of a licensed pharmacist.  
COMAR 10.34.21.03A and C
- ☐ ☐ All unlicensed personnel who perform tasks in the pharmacy receive documented training for the tasks they perform. COMAR 10.34.21.03D, F

All personnel have received training in: (check all that apply) COMAR 10.34.21.03B (3)-(4)

Yes No

- ☐ ☐ Maintaining records
- ☐ ☐ Patient confidentiality
- ☐ ☐ Sanitation, hygiene, infection control
- ☐ ☐ Biohazard precautions
- ☐ ☐ Patient safety and medication errors COMAR 10.34.26.03

Yes No

- ☐ ☐ There is a written ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03E

Comments: \_\_\_\_\_

#### 4. SECURITY COMAR 10.34.05

Yes No

- ☐ ☐ The pharmacy is designed to prevent unauthorized entry when the prescription area is closed during any period that the rest of the establishment is open. (Briefly describe how access is restricted.) COMAR 10.34.05.02A (5)

- ☐ ☐ The pharmacy and/or pharmacy department has a security system.  
COMAR 10.34.05.02A (2)

- ☐ ☐ The permit holder prevents individuals from being in the prescription area when a pharmacist is not immediately available on the premises to provide pharmacy service.  
COMAR 10.34.05.02A (3)

Comments: \_\_\_\_\_

#### 5. PHYSICAL REQUIREMENTS AND EQUIPMENT

Yes No

- ☐ ☐ Pharmacy area is clean, neat, and organized. HO §12-403(b)(11)(ii)2.  
☐ ☐ The pharmacy provides a compounding service (non-sterile procedures).

Yes No

- ☐ ☐ If yes, the pharmacy maintains equipment that enables it to prepare and dispense prescriptions properly within its scope of practice. COMAR 10.34.07.02  
☐ ☐ The pharmacy has a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity. COMAR 10.34.07.01A  
☐ ☐ The pharmacy has hot and cold running water.  
☐ ☐ The medication refrigerator(s) contain only prescription items. COMAR 10.34.07.01B  
☐ ☐ The medication refrigerator(s) have a thermometer. COMAR 10.34.07.01B  
☐ ☐ The current temperature of the medication refrigerator(s) is between (36F-46F). USP  
Temperature \_\_\_\_\_  
☐ ☐ The current temperature of the pharmacy department is between [59 to 86 degrees F].  
COMAR 10.34.05.02A (1) (a)  
Temperature \_\_\_\_\_

Yes No

- ☐ ☐ The pharmacy maintains a library of current reference sources consistent with its scope of practice that is accessible to all appropriate personnel. COMAR 10.34.07.03
- ☐ ☐ The pharmacy has online resources. HO §12-403(b)(15)
- ☐ ☐ The pharmacy possesses the current edition of *The Maryland Pharmacy Laws and Regulations*. HO §12-403(b) (10) (ii)

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## 6. PRESCRIPTION LABELING, FILES, AND STORAGE

Yes No

- ☐ ☐ Hard copy prescription files are maintained chronologically for 5 years. HO §12-403(b) (13)  
The following label requirements are met if a drug is dispensed pursuant to a prescription.  
COMAR 10.34.23.09

Yes No

- ☐ ☐ The name and address of the pharmacy;
- ☐ ☐ The serial number of the prescription;
- ☐ ☐ The date the prescription was dispensed;
- ☐ ☐ The name of the prescriber;
- ☐ ☐ The name of the resident;
- ☐ ☐ The name and strength of the drug or devices;
- ☐ ☐ The quantity of the drug or device;
- ☐ ☐ The required precautionary information regarding controlled substances;
- ☐ ☐ The required cautionary statements or auxiliary labels;
- ☐ ☐ The name of generic manufacturer;
- ☐ ☐ The expiration date is indicated;
- ☐ ☐ (Medications in Parenteral Admixtures) The name and amount of drug(s) added;
- ☐ ☐ (Medications in Parenteral Admixtures) The name of the pharmacist responsible for the admixture;
- ☐ ☐ (Medications in Parenteral Admixtures) The rate of infusion; and
- ☐ ☐ (Medications in Parenteral Admixtures) The frequency of infusion

Yes No

- ☐ ☐ The pharmacist and technician initials are on prescriptions or patient drug profiles or computerized patient records. COMAR 10.34.08.01
- ☐ ☐ Original prescriptions are dispensed within 120 days after the issue date. HO §12-503

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## 7. QUALITY ASSURANCE – PATIENT SAFETY / MEDICATION ERRORS

Yes No

- ☐ ☐ There are written procedures to follow when reporting a suspected medication error to the permit holder, pharmacist, health care facility, or other health care provider.  
COMAR 10.34.26.02

- ☐ ☐ The pharmacy maintains a minimum of two (2) continuous years of records clearly demonstrating the content of annual educational training provided to each member of the pharmacy staff involved in the medication delivery system regarding the role and responsibility of pharmacy staff in preventing medication errors. COMAR 10.34.26.03B

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## 8. CONFIDENTIALITY

Yes No

- ☐ ☐ Confidentiality is maintained in the creation, storage, access, disposal and disclosure of patient records. HO §12-403(b)(13), COMAR 10.34.10.03A and HIPAA Regulations.
- ☐ ☐ Any identifiable information contained in a patient's record is not disclosed unless authorized by the patient, or an order of the court, or as authorized pursuant to HG §4-301 through §4-307. COMAR 10.34.10.03B

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## 9. INVENTORY CONTROL PROCEDURES

Yes No

- ☐ ☐ The pharmacy maintains invoices as required by law for accurate control and accountability of all pharmaceuticals. COMAR 10.34.24.03
- ☐ ☐ The pharmacy has written policies and procedures for the safe handling of drug recalls.  
See [www.recalls.gov](http://www.recalls.gov)
- ☐ ☐ The pharmacy maintains records of all recalls. See [www.recalls.gov](http://www.recalls.gov)
- ☐ ☐ The pharmacy has a written procedure in place for removal of all expired drugs; (both prescription and OTC) COMAR 10.34.12.01

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

#### 10. CONTROLLED SUBSTANCES

Yes No

- ☐ ☐ Hard copy prescription files are maintained chronologically for 5 years. COMAR 10.34.20.03; HO §12-403(b)(13). (CDS-Federal law requires record retention for 7 years)
- ☐ ☐ A perpetual inventory is maintained for Schedule II controlled substances.  
(Recommended)
- ☐ ☐ Schedule II controlled substances are dispersed throughout the stock of non-controlled substances, or stored in such a manner as to obstruct theft or diversion.  
COMAR 10.19.03.12B (2)
- ☐ ☐ The pharmacy has a copy of the most recent required biennial inventory of  
Schedule II- V controlled substances. COMAR 10.19.03.05B  
Inventory date: \_\_\_\_\_
- ☐ ☐ Inventory completed at Opening or Closing (circle one)
- ☐ ☐ The inventories and records of Schedule II-V drugs are maintained and readily  
available. COMAR 10.19.03.05 and 21 CFR 1304.03
- ☐ ☐ Records are kept of all receipts of controlled substances entered into the pharmacy  
inventory (including DEA Form 222 or CSOS orders). COMAR 10.19.03.05
- ☐ ☐ The prescription label for controlled drugs include the following warning:  
"CAUTION Federal law prohibits the transfer of this drug to any person other than  
the patient for whom it was prescribed ", in 6-point type or the Pharmacy utilizes an  
auxiliary label that contains this warning. COMAR 10.19.03.08D (1)
- ☐ ☐ All controlled substances prescriptions bear the name and address of the prescriber and  
patient COMAR 10.19.03.07D(1)
- ☐ ☐ The permit holder or pharmacist designee(s) has written policies and procedures for  
investigating discrepancies and reporting of theft or loss. COMAR 10.19.03.12B (4)

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

#### 11. AUTOMATED MEDICATION SYSTEMS Yes ☐ No ☐ (if No, go to #12)

Yes No

- ☐ ☐ The facility uses an automated device(s) as defined in COMAR 10.34.28.02.  
Written policies and procedures exist for (check all that apply): COMAR 10.34.28.05  
Yes No
  - ☐ ☐ Control of access to the device.
  - ☐ ☐ Accounting for medication added and removed from the system.
  - ☐ ☐ Sufficient safeguards are in place to ensure accurate replenishment of the  
automated medication system. If yes, describe safeguards. COMAR 10.34.28.06

Comments: \_\_\_\_\_

Yes No

- ☐ ☐ Adequate records are maintained for at least two years addressing the following (check all that apply). COMAR 10.34.28.11

Yes No

- ☐ ☐ Maintenance records.  
☐ ☐ System failure reports.  
☐ ☐ Accuracy audits.  
☐ ☐ Quality Assurance Reports.  
☐ ☐ Reports on system access and changes in access.  
☐ ☐ Training records.

Yes No

- ☐ ☐ The pharmacy has records, documents, or other evidence of a quality assurance program regarding the automated medication system in accordance with the requirements of COMAR 10.34.28

Comments: \_\_\_\_\_

**12. OUTSOURCING** Yes ☐ No ☐ (if No, go to #13)

Yes No

- ☐ ☐ The facility outsources the preparation of medications or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02  
☐ ☐ The facility serves as a primary pharmacy outsourcer to other pharmacies. COMAR 10.34.04.02  
☐ ☐ The facility serves as a secondary pharmacy. COMAR 10.34.04.02  
☐ ☐ Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06  
☐ ☐ Documentation is maintained, including the names and locations of the pharmacies, names of pharmacists, and a record of the preparations made. COMAR 10.34.04.03 and .05

Yes No

- ☐ ☐ The permit holder employs an outside agency/business entity for the provision of any pharmacy services, inclusive of staffing, remote order entry, and management. If yes: Name of agency, state of incorporation, service contracted, and State of Maryland License/Permit Number: \_\_\_\_\_  
COMAR 10.34.04.06E

The pharmacist from the primary pharmacy documents in a readily retrievable and identifiable manner (Check all that apply): COMAR 10.34.04.06

Yes No

- ☐ ☐ The prescription order was prepared by a secondary pharmacy.
- ☐ ☐ The name of the secondary pharmacy.
- ☐ ☐ The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.
- ☐ ☐ The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner.
- ☐ ☐ The date on which the prescription order was transmitted to the secondary pharmacy.
- ☐ ☐ The date on which the preparation was sent to the primary pharmacy.
- ☐ ☐ The primary and secondary pharmacies are both licensed in the State of Maryland, or operated by the federal government. COMAR 10.34.04.06F
- ☐ ☐ The primary pharmacy maintains, in a readily retrievable and identifiable manner, a record of preparations received from the secondary pharmacy. COMAR 10.34.04.06G

The permit holder at the secondary pharmacy maintains documentation in a readily retrievable and identifiable manner, which includes (check all that apply):  
COMAR 10.34.04.07

Yes No

- ☐ ☐ Records of the prescription orders transmitted from another pharmacy.
- ☐ ☐ The date on which the prescription order was transmitted from the primary pharmacy.
- ☐ ☐ The name and information identifying the specific location of the primary pharmacy.
- ☐ ☐ The name of the pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner.
- ☐ ☐ The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order.
- ☐ ☐ The name of the pharmacist at the secondary pharmacy who verified/performed the final check of the prescription order.

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_



### 13. DISTRIBUTION

Yes No

- ☐ Sales of prescription drugs other than by patient specific prescription orders exceeds 5% of the pharmacy's annual sales.

If yes, Maryland distributors license # \_\_\_\_\_ COMAR 10.34.22.04.

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### 14. MEDICATION RETURN POLICIES

Yes No

- ☐ There are established written policies related to re-use of returned medications. (COMAR 10.34.10.07) If "no" Provide explanation.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### 15. CONTINGENCY PLANNING

Yes No

- ☐ There are documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### 16. MEDICATION ORDERS (COMAR 10.34.03.12)

- ☐ Medications are dispensed from the pharmacy only in response to medication orders issued by authorized prescribers or by prescriber per institution approved protocols.

### 17. MEDICATION PREPACKAGING AND REPACKAGING (COMAR 10.34.23.08)

Yes No

- ☐ The pharmacy prepares prepackaged or repackaged medications. (If yes complete questions below)
- ☐ The Pharmacist verifies the manual or automated selection of prepackaged and prelabeled doses of medication and the repackaging of medication in unit dose packages or any other form of repackaging performed by pharmacy personnel for accuracy, completeness and appropriateness.

The labeling for prepackaged or repackaged medications includes:

Yes No

- ☐ Brand and generic name of the medication;
- ☐ Strength of the medication, if appropriate;
- ☐ Name of the distributor or manufacturer;
- ☐ Lot number of distributor or manufacturer (or lot number assigned by pharmacy); and
- ☐ Expiration date of the medication
- ☐ If the pharmacy uses a lot number and expiration date assigned by the pharmacy instead of the distributor or manufacturer information, a master log is kept which identifies all of the repackaged drugs within the facility.  
The master log includes:

Yes No

- ☐ Name of drug;
- ☐ Strength of drug;
- ☐ Name of manufacturer;
- ☐ Lot number assigned by pharmacy;
- ☐ Quantity repackaged;
- ☐ Expiration date;
- ☐ Manufacturer's expiration date;
- ☐ Lot number assigned by the distributor or manufacturer;
- ☐ Date of repackaging;
- ☐ Name of person repackaging; and
- ☐ Name of verifying pharmacist.
- ☐ A written policy exists regarding what medications and quantities are to be contained in emergency drug kits as well as procedures for replacing medications.
- ☐ A written policy exists regarding what medications and quantities are to be contained in interim drug box as well as procedures for restocking medications.

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## 17. CONSULTANT SERVICES

Yes No

- ☐ There are written policies for and documentation of timely medication review by consulting pharmacists at all sites.

## 18. DELIVERY SERVICES

- ☐ There are policies for and documentation of timely delivery of medications to all sites.

[illegible]Pharmacist Name: \_\_\_\_\_ Date: \_\_\_\_\_  
(Print)

Revised 09/01/08